SIEMENS K955743 JUL - 8 1995

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING A DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The Siemens SC 6000 & SC 6000 P Portable Bedside Monitoring Systems with Cardiac Arrhythmia Detection Option is an enhanced version of the Siemens SC 6000 & SC 6000 P Portable Bedside Monitoring Systems granted premarket approval under 510 K file number K944350. The enhanced system has modified software to support added features.

The enhanced software is equivalent to the software used in the Siemens SC 9000 patient monitor. The Siemens SC 9000 was granted premarket approval under 510 K file number K946306. The Intended Use Statement for the enhanced software is the same as the Intended Use as the SC 9000 patient monitor.

Intended Use Statement:

The intended use of this device is to measure heart rate, respiration rate, invasive pressure, noninvasive pressure, temperature, arterial oxygen saturation and provide ECG ectopic beat and arrhythmic rhythm detection. This device will produce visual and aural alarms if any of these parameters vary beyond preset limits and produce timed or alarm recordings. This device will connect to the Siemens SIRENET network.

Intended Operator:

The SC 6000/SC 6000P/R 50 Portable Patient Monitoring System is intended to be used be Healthcare providers, i.e. Physicians, Nurses, and Technicians.

Intended Patient Populations:

The parameters monitored by the SC 6000P are intended for use with adult and pediatric populations with the exception of the arrhythmia option which is intended for adults patients only.

Intended Use Environment:

The SC 6000/SC 6000P/R 50 Portable Patient Monitoring System is intended to be used in the environment where patient care is provided by Healthcare Professionals.

Performance Standard:

None established under Section 514 or Section 358.

Siemens Medical Systems, Inc. **Revisied 4/11/96**

Electromedical Group
16 Electronics Avenue
Danvers, MA 01923
USA

Tel: (508) 750-7500
Fax: (508) 777-3398
Telex: 511958 (Siemensm SD)

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General Information:

A. Trade Name:

Siemens SC 6000 & SC 6000 P Portable Bedside Monitoring Systems with Cardiac Arrhythmia Detection Option

B. Common Name, Classification Number, Class and Regulation Number:

Common Name	Classification Number	Class	Regulation Number
Cardiac monitor	74DRT	II	21 CFR 870.2300
Pulse rate monitor	74BWS	II	21 CFR 870.2300
Pulse oximeter	74DQA	II	21 CFR 870.2700
Breathing frequency monitor	73BZQ	II	21 CFR 868.2375
Clinical electronic thermometer	80BWX	II	21 CFR 880.2910
Indwelling blood pressure monitor	74CAA	II	21 CFR 870.1110
Noninvasive blood pressure monitor	74DXN	II	21 CFR 870.1130
Arrhythmia detector & Alarm	74DSI	III	21 CFR 870.1025

C: Establishment registration Number:

1220063

D: Establishment Name and Address:

Siemens Medical
Electronics, Inc.
16 Electronics Avenue
Danvers, MA 01923

E: New or Modification:

The Siemens SC 6000 & SC 6000 P with Optional Cardiac Arrhythmia Detection System is an enhanced software version of the Siemens SC 6000 & SC 6000 P portable patient monitor. The enhanced version adds cardiac arrhythmia monitoring and a number of user convenience features. The Intended Use Statement for the enhanced software is the same as the Intended Use as the SC 9000 patient monitor. The Siemens SC 9000 was granted premarket approval under 510 K file number K946306.

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The enhanced software (version VA4-1XX) is compatible with previously sold versions of the monitors. A retrofit will be offered to the owners of units with previous software versions.

Following are descriptions of the SC 6000 and SC 6000 P systems enhancements covered in this submission:

Cardiac Arrhythmia Detection Option:

The Siemens SC 6000 & SC 6000 P offer an Optional Cardiac Arrhythmia Detection System that detects, alarms both visually and audibly and generates recordings for ventricular tachicardia(VT) and PVCs/min. Prior to this enhancement the Siemens SC 6000 & SC 6000 P detected, alarmed both visually and audibly and generated recordings for only the cardiac arrhythmias of ventricular fibrillation and asystole.

The Optional Cardiac Arrhythmia Detection System functionality is achieved with a software upgrade.

The Siemens SC 6000 & SC 6000 P Optional Cardiac Arrhythmia Detection System is equivalent to the Cardiac Arrhythmia Detection System of the Siemens SC 9000. The Siemens SC 9000 was granted premarket approval under 510 K file number K946306. The SC 9000's Cardiac Arrhythmia Detection system has been integrated into the SC 6000 & SC 6000 P software(K944350).

To support substantial equivalence to the predicate SC 9000 system the SC 6000 & SC 6000 P Cardiac Arrhythmia Detection system has been tested using the test and results reporting called out in the AAMI (ECAR-1987) "Recommended Practice for Testing and Reporting Performance Results of Ventricular Arrhythmia Detection Algorithms" and the FDA "Guidelines For Submitting Data In Support of Premarket Notification (510(k)) Applications for Arrhythmia Detectors"(1990).

For a summary and complete listing of all the Cardiac Arrhythmia Detection Options validation tests and results refer to Exhibit R, sections;

- IRIS Arrhyhtmia Test
- QRS Classifiaciton Performance
- Consecutive VEB Performance
- Ventricular Fibrillation Performance
- Ventricular Tachicardia Performance.

For details concerning Cardiac Arrhythmia Detection Option consult Exhibit G, Users Guide.

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USA
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Continuos Waveform Recordings:

The SC 6000 and SC 6000 P systems can generate and terminate user initiated continuous recordings on local R50, and networked S60 and S220 recorders. Continuous recording functionality is provided so a permanent long term record can be made of a patients physiologic parameters and waveforms.

The Continuos Waveform Recordings functionality is achieved with a software upgrade.

For details concerning the Continuos Waveform Recordings consult Exhibit G, Users Guide.

For details concerning the Continuos Waveform Recordings performance validation testing consult Exhibit R.

Trend Recordings:

The SC 6000 and SC 6000 P systems can generate and terminate user initiated trend recordings on a local R50 recorder. Trend recording functionality is provided so a permanent record can be made of a patients physiologic parameter trends.

The Trend Waveform Recording functionality is achieved with a software upgrade.

For details concerning the Trend Recordings consult Exhibit G, Users Guide.

For details concerning the Trend Recordings validation testing consult Exhibit R.

Diagnostic Log Recordings:

The SC 6000 and SC 6000 P systems can generate and terminate user initiated Diagnostic recordings on a local R50 recorder. Diagnostic recording functionality is provided so a permanent record can be made of the monitors diagnostic log.

The Diagnostic Log Recording functionality is achieved with a software upgrade.

For details concerning the Diagnostic Log Recordings consult Exhibit G, Users Guide.

For details concerning the Diagnostic Log Recordings validation testing consult Exhibit R.

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User Initiated Stored Recording Dump:

The SC 6000 and SC 6000 P systems can generate and terminate a user initiated dump of stored recordings on a local R50 recorder. The user initiated stored recording dump functionality is provided so a permanent record can be made of the stored recordings at a time convenient to the user.

The user initiated stored recording dump functionality is achieved with a software upgrade.

For details concerning the User Initiated Stored Recording Dump consult Exhibit G, Users Guide.

For details concerning the User Initiated Stored Recording Dump validation testing consult Exhibit R.

Siemens SC 9015 Display support:

The SC 6000 and SC 6000 P display can be shown locally on the units integrated 6" diagonal display or remotely on the Siemens 9015 Display's(K946306) larger 15" diagonal video monitor. The ability to show the SC 6000 or SC 6000 P's display on the larger Siemens SC 9015 is provided for better viewablity.

The Siemens SC 9015 Display support is achieved with a software upgrade.

For details concerning the Siemens SC 9015 Display support consult Exhibit G, Users Guide.

For details concerning the Siemens SC 9015 Display support validation testing consult Exhibit R.

Temperature Alarms:

The SC 6000 and SC 6000 P can generate visual and aural alarms and recordings if the temperature varies beyond preset limits. Prior to this enhancement temperature alarms where not supported on the SC 600 and SC 6000 P.

The default temperature alarm limits, setup range and auto set range is similar to those used by the predicate SC 9000 (K K946306). Refer to table 1.

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Monitor	Default Upper Limit	Default Lower Limit	Setup Range	Auto Set Range
SC 6000/P	39 °C (102 °F)	34 °C (94 °F)	17 to + 50 °C (62.6 to 122 °F)	+ - 7%
SC 9000	39 °C (102 °F)	34 °C (94 °F)	0 to + 50 °C (32 to 122 °F)	+ - 7%

Table 1: Comparison of SC 6000 Temperature alarms to Predicate SC 9000(K K946306).

The Temperature Alarms are achieved with a software upgrade.

For details concerning the Temperature Alarms consult Exhibit G, Users Guide.

For details concerning the Temperature Alarms validation testing consult Exhibit R.

User Selectable Temperature Units:

The SC 6000 and SC 6000 P can display temperature using °Celsius or °Fahrenheit temperature units. Prior to this enhancement the SC 600 and SC 6000 P only displayed temperature in °C. The ability to show the temperature in °F or °C is for user convenience.

The User Selectable Temperature Units functionality is achieved with a software upgrade.

For details concerning the User Selectable Temperature Units consult Exhibit G, Users Guide.

For details concerning the User Selectable Temperature Units validation testing consult Exhibit R.

Configurable SpO2 Response Times:

The SC 6000 and SC 6000 P have two user selectable response times for SpO2 changes. Normal response time will display 90% of a SpO2 change in 15 seconds and Fast response time will display 90% of a SpO2 change in 6 beats. Prior to this enhancement the SC 6000 and SC 6000 P had only the Normal response time. The fast response time was added for patients where a quicker reporting of O2 desaturation is required.

The Configurable SpO2 Response Times is achieved with a software upgrade.

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Enhanced respiration rate tracking during periods of respiration rate slow downs: When breathing stops, the respiration rate algorithm now updates at a rate equal to the expected respiration rate. This provides an accurate indication of the respiration rate. For example a respiration rate of 15 breaths per minute(bpm) exists prior to the cessation of breathing. The respiration rate will change from 15 to 14 bpm after 4 seconds. Prior to this enhancement the respiration rate would stay at 15 bpm until a new breath was detected or if no breaths occurred drop to 0 bpm after 30 seconds.

Narrower respiration signal band width : The bandwidth of the processed and displayed respiration signal is 0.25 to 3.0 Hz. Prior to this enhancement the bandwidth was 0.05 to 7.0 Hz. The 0.05 to 7.0 Hz bandwidth has a slow recovery time for baseline offsets and passes cardiogenic artifact to the respiration rate algorithm. A slow recovery time to baseline offsets can result in missed breath detections and cardiogenic artifact can result in false breath detections.

All the Respiration Rate Algorithm Improvements are achieved with a software upgrade.

For details concerning the Respiration Algorithm Improvements validation testing consult Exhibit R.

ECG Baseline Recovery Improvement:

The performance of SC 6000 and SC 6000 P's ECG Baseline Recovery has been improved to center the ECG within 5 seconds after the ECG drifts out of the display range. Prior to this enhancement the ECG was not centered unless it drifted outside of the amplifiers range.

The ECG Baseline Recovery Improvement is achieved with a software upgrade.

For details concerning the ECG Baseline Recovery Improvement validation testing consult Exhibit R.

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II. SAFETY AND EFFECTIVENESS INFORMATION

ELECTRICAL:

Complies with Standards - IEC 601-1, Safety Class 1, Type CF
UL 544 and CSA C22.2 No.125

The results of the environmental, electrical safety, and mechanical test results which were performed on the monitors are presented in Appendix 1, Exhibit N.

OPERATION:

The device labeling contains instructions for use which assures safe and effective use of the device.

CAUTION: Federal law in the United States restricts this device to sale by, or on the order of a physician. All Siemens bedside monitors, parameter cartridges, central displays, recorders, ancillary displays, peripheral equipment, and accessories are intended for the use only by qualified medical personnel. Patient monitoring equipment, however sophisticated, should never be used as a substitute for human care, attention, and critical judgment that only trained health care professionals can provide.

DEVELOPMENT:

Medical device development is conducted in accordance with an approved Siemens Product Planning Process. Product specifications, hazards analysis, software development plan and device test plan are required parts of the device development process. Qualification test results which demonstrate that the device performs in accordance with its specification are required before product release.

III. SUBSTANTIAL EQUIVALENCE

The Siemens SC 6000 & SC 6000 P with Optional Cardiac Arrhythmia Detection System use the same hardware with enhanced software to accommodate the cardiac arrhythmia monitoring and the other features covered in this submittal. performance specifications for these features are equivalent to the performance specifications of the Siemens SC 9000 patient monitor. The Siemens SC 9000 was granted premarket approval under 510 K file number K946306.

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